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April 9, 2001

510(k) Summary
As Required by 21 section 807.92 (c)

1-Submitter Name: Marina Medical Instruments, Inc.
2-Address: 1128 North Northlake Dr
Hollywood, FL 33019
3-Phone: (954) 924- 4418
4-Fax: (954) 924- 4419
5-Contact Person: Jihad Mansour
6-Date summary prepared: January 29th, 2001 **revised** April 9th, 2001
7-Device Trade or Proprietary Name: IMUZ
8-Device Common or usual name: Uterine Manipulator Injector Cannula
9-Device Classification Name: Cannula, Manipulator/Injector, Uterine
10-Substantial Equivalency is claimed against the following device:

- Zumi-4.5™- Zinnanti Uterine Manipulator Injector

11-Description of the Device:

The device is to be used by physicians in hospitals
IMUZ is both a uterine manipulator and a uterine injector for single use. This is a sterile (by ethylene oxide) disposable product made out of clear plastic, which meets USP recommendations for implant testing. This product is designed with a double lumen, one for inflation of a 10cc intrauterine cuff and the other for injection of fluid through a distal endport. The product is curved to facilitate forward uterine manipulation. The product features an inflation valve and pilot balloon assembly, an endport, an inflatable cuff, centimeters depth markings, cervical stop, a removable rigid plastic handle and a luer fitting to accommodate a syringe. The instrument has a length of 13 inches (33cm) and an outer diameter of 4.5mm (.18 inches)

12-Intended use of the device:

This device is indicated for use in Diagnostic Laparotomy, Minilaparotomy, Fertility, Examinations, and Salpingoplastic procedures where manipulation of the uterus is required. This product also facilitates the sealing of the cervical os while providing a fluid or air injection port.

13-Safety and Effectiveness of the device:

This device (**IMUZ**) is safe and effective as the other predicate device cited above. This is better expressed in the tabulated comparison (Paragraph 14 below)

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14-Summary comparing technological characteristics with other predicate device:

Please find below a tabulated comparison supporting that **IMUZ** is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached.

FDA file reference number	510k 941458
Attachments inside notification submission file	REFER TO TABLE ON PAGE 11 OF 12 FOR DETAILS
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**
Indications for use	Identical
Target population	Identical
Design	Identical
Materials	Identical
Performance	Identical
Sterility	Similar (Ethylene Oxide but different parameters)
Biocompatibility	Identical
Mechanical safety	Identical
Chemical safety	Identical
Anatomical sites	Identical
Human factors	Identical
Energy used and/or delivered	Identical
Compatibility with environment and other devices	Identical
Where used	Identical
Standards met	Identical
Electrical safety	Identical (not applicable)
Thermal safety	Identical (not applicable)
Radiation safety	Identical (not applicable)

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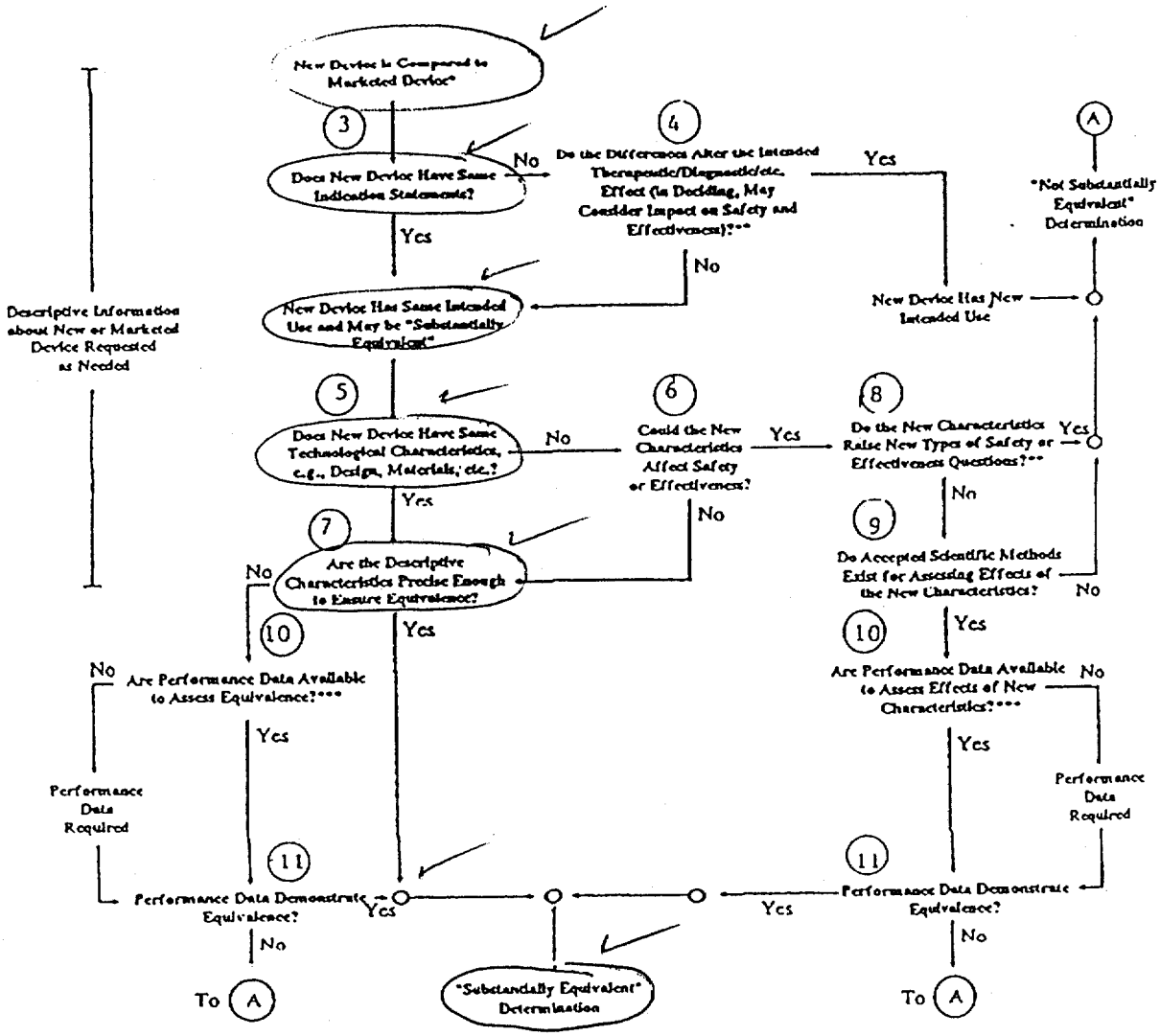
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



- 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 1 2001

Jihad Mansour, MSQA, BE, LA, RAC
Quality and Regulatory Manager
Marina Medical Instruments, Inc.
1128 North Northlake Drive
HOLLYWOOD FL 33019

Re: K010296
IMUZ™ Uterine Manipulator Injector Cannula
Dated: January 29, 2001
Received: January 31, 2001
Unclassified/Procode: 85 LKF

Dear Mr. Mansour:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K010296

Device Name: IMUZ

Indications For Use:

THIS UTERINE MANIPULATOR INJECTOR CANNULA (IMUZ) IS INDICATED FOR USE IN DIAGNOSTIC LAPAROTOMY, MINILAPAROTOMY, FERTILITY, EXAMINATIONS, AND SALPINGOPLASTIC PROCEDURES WHERE MANIPULATION OF THE UTERUS IS REQUIRED.

THIS DEVICE ALSO FACILITATES THE SEALING OF THE CERVICAL OS WHILE PROVIDING A FLUID OR AIR INJECTION PORT

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Lagan
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010296